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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,741	03/31/2004	Alexander A. Krakovsky		5136

7590 10/12/2006
John R. Ross
P.O. Box 2138
Del Mar, CA 92014

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,741

Applicant(s)

KRAKOVSKY, ALEXANDER A.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20060627.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 27 is objected to because of the following informalities: "impmlanting" should read "implanting". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although exemplary embodiments are shown in Figures 3A and 3B, support for the negative limitations of "at least five minutes", "not less than 2.5 Volts and not greater than 5 Volts", "not less than 1 Hz and not greater than 2 Hz", "less than 20 minutes", and "monotonically" (i.e. excludes a value less than the previous value) was not found by the examiner. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under

35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krakovsky et al. (US 5,454,840, hereinafter "Krakovsky") in view of Cameron et al. (US 2004/0088021, hereinafter "Cameron"). Krakovsky discloses the essential features of the claimed invention including the following:

5. In regards to claims 12, 19 and 30, Krakovsky discloses a method of correcting impotency comprising implanting a programmable stimulator having a control device with a start function (abstract, Figs. 3 and 4), surgically implanting the stimulator (Fig. 5), providing an electrical connection between the electrode and stimulator (48), performing a parameter selection test (col. 4, line 20), programming the stimulator to produce a series of pulses wherein the desired result is an erection lasting five minutes (Fig. 13), and providing a control unit adapted for use by the person (Fig. 4). Krakovsky does not disclose implanting the electrodes in an epidural region of a sacrum or applying the treatment to a female for increased sexual desire. Cameron teaches of providing a sexual treatment device with electrodes implanted in the sacrum (abstract)

to target the source of the nerves that affect sexual function, and applying treatment to females for increased sexual desire (par. 0002 defines low sexual desire as a sexual dysfunction and par. 0001 discloses treating sexual dysfunctions) to improve the quality-of-life of the targeted patient population. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Krakovsky's invention with electrodes implanted in the sacrum to target the source of the nerves that affect sexual function, and applying treatment to females for increased sexual desire to improve the quality-of-life of the targeted patient population.

6. In regards to claims 13, 20 and 31, the pulse heights are between 2.5 and 5 volts (Fig. 13).

7. In regards to claims 14, 21 and 32, the pulse widths are about 0.1 sec. (Fig. 13).

8. In regards to claims 15, 22 and 33, the pulse frequency is between 1 and 2 Hz (Fig. 13).

9. In regards to claims 16, 23 and 34, the parameters are chosen to provide a result for a period of less than 20 minutes (Fig. 13).

10. In regards to claims 17, 18, 24, 25, 35 and 36, the pulse heights and frequencies are increased monotonically during the action period (Fig. 13).

11. In regards to claims 26 and 37, Krakovsky discloses the essential features of the claimed invention except for electrodes on opposite sides of the centerline of the epidural space. Cameron teaches of providing electrodes on opposite sides of the centerline of the epidural space (Fig. 4) to affect both sides of the human body and adequately stimulate a maximum of nerves associated with sexual function. Therefore,

it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Krakovsky's invention with electrodes on opposite sides of the centerline of the epidural space to affect both sides of the human body and adequately stimulate a maximum of nerves associated with sexual function.

12. In regards to claims 27-29, Krakovsky discloses a stimulator including a pump for pumping stored drugs into the patient (Fig. 10) wherein two of the listed drugs are delivered (col. 5, lines 30-60).

Response to Arguments

13. Applicant's arguments with respect to claims 12-37 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

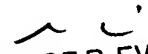
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK


9/29/06


GEORGE R. EVANISKO
PRIMARY EXAMINER

10/5/06